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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,618	12/22/2005	Dov Tamarkin	113873.124 US2	9411
23483	7590	09/14/2009		
WILMERHALE/BOSTON				
60 STATE STREET				
BOSTON, MA 02109				
EXAMINER				
VU, JAKE MINH				
ART UNIT		PAPER NUMBER		
1618				
NOTIFICATION DATE		DELIVERY MODE		
09/14/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

**Application No.**

10/532,618

**Applicant(s)**

TAMARKIN ET AL.

**Examiner**

Jake M. Vu

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 8-19, 21-32, 34, 35, 37, 47, 50, 57, 60, 62-78, 80, 83, 85 and 87 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16, 19, 21-24, 27, 29-32, 34, 35, 37, 50, 60, 64 and 65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-6,8-15,17,18,25,26,28,47,57,66-78,80,83,85 and 87.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/21/08,6/17/08,2/2/07,12/22/05.

### **DETAILED ACTION**

Receipt is acknowledged of Applicant's Restriction Response filed on 01/12/2009; and Information Disclosure Statements filed on 08/21/2008, 06/17/2008, 02/02/2007, and 12/22/2005.

- Claims 1-6, 8-19, 21-32, 34-35, 37, 47, 50, 57, 60, 62-78, 80, 83, 85, and 87 are pending in the instant application.
- Claims 1-6, 8-15, 17-18, 25-26, 28, 47, 57, 62-63, 66-78, 80, 83, 85, 87 are withdrawn from consideration.

### ***Election/Restrictions***

Applicant's election of Group II (claims 16-19, 21-32, 34, 35, 37, 47, 50, 57, 60, 62-65) and election species of: 20-75% by weight of hydrophobic solvent, mineral oils, essentially non-ionic surfactant, fucidic acid, iodine compounds, and wound, in the reply filed on 01/12/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It's unclear how a foamable composition with the percentages of 20-75% hydrophobic solvent, 80-98% of water, 0.1-5% foam adjuvant, 0.1-5% surface active agent, 0.1-5% of water gelling agent is mathematically possible, since the lowest percentages of the five ingredients equal 100.3%.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 19, 21-24, 27, 29-32, 34, 35, 37, 50, 60 and 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over ABRAM (US 6,730,288, in which PCT pub date is 03/23/2000) in view of REED et al (US 6,299,900) and SHAHINPOOR et al (US 2002/0182162).

Applicant's claims are directed to a composition comprising of: 20-75% of a liquid, non-volatile hydrophobic solvent, such as mineral oil; 80-98% of water; 0.1-5% of

foam adjuvant agent; 0.1-5% of non-ionic surface active agent; 0.1-5% of water gelling agent; an active agent, such as fucidic acid (also known as fusidic acid), which is a bacteriostatic antibiotic; and a propellant. Additional limitations include: antioxidants; penetration enhancer; sunscreen agent; iodine compounds.

ABRAM teaches a composition comprising of: 20-50% (see col. 2, line 58) of a liquid, non-volatile hydrophobic solvent, such as mineral oil (see col. 2, line 43); water (see col. 4, Table 1), which are about 80%; 0.5-2% (see col. 4, line 8) of foam adjuvant agent, such as long chain alcohol (see col. 4, line 1-2), which is a fatty alcohol; 2-5% (see col. 3, line 43) of non-ionic surface active agent (see col. 2, line 63-65); viscosity modifying agent (see col. 4, line 19), which reads on water gelling agent; active agents, such as an antibacterial agent (see col. 2, line 2) or minoxidil (see col. 1, line 18); and a propellant (see col. 2, line 25-28). Additional disclosures include: aerosol foam base are well known in the art (see col. 2, line 21-22); antioxidants (see col. 4, line 18); penetration enhancer (see col. 18-19).

ABRAM does not specifically teach using an active agent, such as fucidic acid (also known as fusidic acid), which is a bacteriostatic antibiotic; sunscreen agent; iodine compounds.

REED teaches that antibacterial antibiotic agents, such as fusidic acid and iodine compounds (see col. 8, line 25 and 27) are well known to be used as active agents in transdermal drug delivery (see col. 4, line 67) that are foam aerosol propellant (see col. 1, line 22; col. 11, line 22).

SHAHINPOOR teaches active agents, such as minoxidil and sildenafil, enhances hair growth or diminish hair loss (see abstract), which reads on disorder of the hair follicle, wherein the drugs may be mixed with a dermatological carrier vehicle (see [0013]). Additional disclosures include: dermatological carrier, such as a moisturizing carrier; mineral oil, which is an emollient; cetyl alcohol, which is a fatty acid with 16 carbons and a therapeutically foam adjuvant; dimethicone, which is a therapeutically active oil; propylene glycol, which is a penetration enhancer; sunscreen (see [0013]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate fucidic acid and iodine compounds into ABRAM's composition. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because ABRAM teaches using antibacterial antibiotic, in which fucidic acid and iodine compounds are antibacterial antibiotic agents.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate sunscreen agent into ABRAM's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because a sunscreen agent would protect the skin of the bald-headed patient who is using minoxidil, which is Rogaine, a the active agent, and reasonably would have expected success because both references dealt with the active agent minoxidil.

The references do not specifically teach adding the water gelling agent in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is

clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as the thickness of the foam. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.



***Telephonic Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/  
Primary Examiner, Art Unit 1618